

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0648346	<b>(X3) Date Survey Completed</b>  08/27/2018
<b>Name of Provider or Supplier</b>  Saline County Health Department	<b>Street Address, City, State</b>  125 West Elm, Salina, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) documentation, patient test logs, and interview with the Technical Consultant (TC) and Testing Personnel (TP) #3, the laboratory failed to twice annually verify the accuracy of the vaginal pH, whiff, and potassium hydroxide (KOH) tests, which are tests and procedures that are not included in subpart I of this part. Findings Include: 1. Review of the laboratory's test logs titled "Wet Prep Result Log" found documentation indicating the laboratory performs vaginal pH, whiff, and KOH testing. TP #3 confirmed the laboratory performs these tests. 2. Review of the laboratory's 2018, 2017, and 2016 AAB PT documentation found the laboratory does not participate in PT for the tests vaginal pH, whiff, and KOH. 3. The TC and TP #3 confirmed the laboratory does not participate in PT for the tests vaginal pH, whiff and KOH. The Surveyor requested the laboratory's method accuracy verification documentation from the TC and TP #3. The TC and TP #3 stated the laboratory had not performed method accuracy verifications for the tests vaginal pH, whiff, and KOH in 2018, 2017, and 2016. The interview occurred 08/27/2018 at 8:57 AM.</p>
<b>D5485</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(h)</p> <p>If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.</p>

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's quality control (QC) documentation, policies and procedures, and interview with the Technical Consultant (TC) and Testing Personnel (TP) #3, the laboratory failed to perform and document an alternative controls that detect immediate errors and monitor test system performance over time. Findings Include: 1. Review of the laboratory's QC documentation for 2018, 2017, and 2016 failed to find documentation of alternative QC for the tests wet preparation, potassium hydroxide (KOH) preparation, whiff preparation, and vaginal pH. 2. Review of the laboratory's policies and procedures titled "Wet Mount Procedure for Trichomonas Vaginalis", "Amine (Whiff) Test", and "Vaginal pH Test" found the following statements: Wet Mount Procedure for Trichomonas Vaginalis Quality Control: None Amine (Whiff) Test Quality Control: There is no quality control test material currently available. Vaginal pH Test No reference to quality control was present in the procedure. 3. The TC and TP #3 confirmed the laboratory had not performed or documented alternative QC for the tests wet preparation, KOH preparation, Whiff test, or vaginal pH in 2018, 2017, and 2016. The interview occurred 08/27/2018 at 9:06 AM.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's quality assessment (QA) policy, QA documentation, and interview with Testing Personnel (TP) #3, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings Include: 1. Review of the laboratory's policy titled "Quality Assessment Plan" found the laboratory the following statements: Process Integral to monitoring/review of these systems involves the following activities: - Ongoing monitoring of each testing process in order to identify or assess errors or potential problems that could result in errors; (QA Monitoring/Review sheets are available to record monitoring/review for: proficiency testing, personnel, policy and procedure manuals, patient test management, hematology, coagulation, chemistry, blood bank, serology, and urinalysis. Communication/complaint logs are available.) 2. Review of the laboratory's QA documentation for 2018 titled "Quality Assessment Monitors" and "Routine Quality Assurance Monitoring 2018" found QA activities had only been performed and documented in July 2018. No additional documentation of QA activities for the rest of 2018 were present. 3. TP #3 confirmed the laboratory had not followed the QA policy and documented QA activities in 2018 other than in July 2018. The interview occurred 08/27/2018 at 9:38 AM.

**D5801**

**TEST REPORT**  
 CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's patient test records, final test reports, and interview with Testing Personnel (TP) #3, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. Findings Include: 1. Review of the laboratory's wet preparation, vaginal pH, and whiff test patient logs titled "Wet Prep Result Log" found the following results documented: 04/16/2018 at 1:40 PM pH: 4.5 Whiff Test: Neg Yeast: Neg Trich: Neg Clue Cells: Neg 2. Review of the laboratory's final test reports located in the patient's paper medical record found no vaginal pH, whiff test, or wet preparation results documented between December 2015 and the date of survey. 3. TP #3 confirmed the patient's vaginal pH, whiff, and wet preparation results from 04/16/2018 were not present in the patient's chart. The interview occurred 08/27/2018 at 9:52 AM.